

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<u>AETNA INC. AND AETNA HEALTH</u>	:	
MANAGEMENT, LLC,	:	
Plaintiffs,	:	
v.	:	CIVIL ACTION NO. 17-4812
INSYS THERAPEUTICS, INC., <i>et al.</i> ,	:	
<u>Defendants.</u>	:	

Rufe, J.

August 23, 2018

MEMORANDUM OPINION

Plaintiffs Aetna Inc. and Aetna Health Management, LLC (collectively, “Aetna” or “Plaintiffs”), filed suit against Insys Therapeutics, Inc., several of its current and former executives, and multiple named and unnamed physicians, alleging a conspiracy to fraudulently induce Aetna into providing reimbursement for off-label prescriptions of Insys’s opioid product, Subsys. Insys moves to dismiss Aetna’s common law claims on federal preemption and state law grounds and moves to strike certain allegations from the Complaint. Former sales executives Joseph Rowan and Sunrise Lee move to dismiss Aetna’s claims against them for lack of personal jurisdiction and failure to state a claim. Lee also moves to dismiss for insufficient service of process. Dr. Steve Fanto moves to dismiss for lack of personal jurisdiction. For the reasons discussed below, Insys’s motion will be denied in part and granted in part, and Fanto, Rowan, and Lee’s motions will be granted.

I. BACKGROUND¹

Defendant Insys is the Arizona-based manufacturer of Subsys, a formulation of the highly potent opioid, fentanyl, that is administered to patients sublingually (under the tongue) as a spray. Since its launch in 2012, Subsys has only been approved by the United States Food and

¹ The following facts, alleged in the Complaint, are assumed to be true for purposes of this Motion unless otherwise stated.

Drug Administration (“FDA”) for a single narrow indication: breakthrough cancer pain in patients who have failed one or more other opioid therapies. Subsys was classified by the FDA as a transmucosal immediate-release fentanyl (“TIRF”) product, and has been subject to special restrictions due to its high potential for addiction and abuse.

Plaintiff Aetna Inc., a Pennsylvania corporation with its principal place of business in Hartford, Connecticut, is a health management organization that provides health payment benefits to members throughout the United States. Plaintiff Aetna Health Management, LLC, a Delaware limited liability company, is a subsidiary of Aetna Inc. that develops and operates group health insurance products and pays claims and benefits incurred by Aetna members, including pharmacy claims for prescription drugs.

Subsys was not listed among the drugs approved for reimbursement in Aetna’s formularies. To obtain coverage for prescriptions of Subsys, Aetna required its member patients to obtain prior authorization from its Pharmacy Management Precertification Unit (the “PMPU”), which applied the following criteria, with limited exceptions,² for precertification: (1) documented diagnosis of cancer and concomitant use of a long acting opioid therapy; and (2) documented contraindication or intolerance or allergy or failure of an adequate trial of one week of a preferred generic fentanyl transmucosal lozenge. Treating physicians could contact Aetna to obtain a medical exception from these requirements based on medical necessity.

Despite Subsys’s limited FDA-approved indication, the restrictions placed on its distribution and coverage by the FDA and insurers, and the availability of less expensive generic TIRF alternatives, the drug gained a substantial share of the TIRF market within a few years of

² California patients could obtain coverage for Subsys with a diagnosis of a terminal illness other than cancer.

its launch. While sales of Subsys in 2012 were only \$14.3 million, sales increased more than 700% in 2013 and exceeded more than \$300 million by 2014.

Aetna alleges that the rapid increase in Insys's sales was due to a two-pronged scheme in which Insys encouraged physicians to overprescribe Subsys for non-FDA approved (or "off-label") uses and defrauded insurers into providing coverage for the off-label prescriptions. Specifically, Plaintiffs allege that Insys targeted its promotional efforts toward physicians who did not treat cancer patients but frequently prescribed TIRFs, and recruited physicians willing to write large numbers of Subsys prescriptions into Insys's speaker program, under which speakers received substantial payments as honoraria. To increase the rate of reimbursement for Subsys prescriptions, Insys established a pre-authorization department ("PAD") based in Chandler, Arizona that communicated directly with insurers, including Aetna. Insys distributed "opt-in" forms to medical offices that authorized prescribers to send patients' medical information to the PAD, allowing the PAD staff to discuss patients' medical conditions and histories with the insurers. Aetna alleges that the PAD used this information to impersonate personnel working at physicians' offices and disguised the area code of the PAD facility during phone calls to avoid detection. To meet pre-certification requirements, the PAD staff allegedly misrepresented to Aetna that the patients receiving Subsys prescriptions were suffering from cancer and had failed other therapies. Insys also hired Area Business Liaisons ("ABLs") to work directly in the offices of certain physician offices to assist the PAD in obtaining prior authorizations for Subsys.

In several state and federal investigations conducted between 2015 and 2017, a number of physicians who had prescribed Subsys to patients admitted that they had prescribed the drug inappropriately and that they had received payments from Insys as part of its speaker program.

According to an internal review conducted by Aetna in the fall of 2015, the majority of Aetna members who had received prior authorization for Subsys did not have a cancer diagnosis.

A. Lee and Rowan

Defendants Lee and Rowan were sales executives at Insys responsible for the promotion of Subsys to potential prescribers. Rowan, who resided in Florida, served as Regional Sales Manager for the Southeast Region and Regional Director for the Eastern Region. Lee, who resided and continues to reside in Michigan, served as Regional Sales Manager for the Mid-Atlantic Region, Regional Director for the Central Region, and Regional Director for the West Region. Plaintiffs allege that Lee, Rowan, and others provided payments and “other forms of kickbacks” through Insys’s speaker program to health care providers who agreed to prescribe Subsys off-label. Plaintiffs also allege that some practitioners who received speaking fees and prescribed Subsys for off-label use were located in Pennsylvania, including one prescriber specifically identified in the Complaint as “Prescriber 2.”³ In addition, Plaintiffs allege that Lee, Rowan, and others “directed PAD staff to obtain and assist practitioners in obtaining the information required to fill out opt-in forms to the program.”⁴

B. Fanto

Fanto is a physician who operated a medical practice in Arizona.⁵ Aetna alleges that Fanto conspired with Insys to defraud Aetna into paying for approximately \$96,000 of Subsys for off-label uses.⁶ Specifically, Aetna alleges that Fanto prescribed Subsys to patients who did not have cancer, and was paid approximately \$234,000 for participating in Insys’s Speaker

³ Compl. at ¶¶ 219-223.

⁴ *Id.* at ¶ 117.

⁵ *Id.* at ¶ 24; Fanto Aff. ¶¶ 20-26.

⁶ Compl. at ¶ 205.

Program.⁷ Aetna further alleges that Fanto sent patient medical records to Insys's PAD, which he knew would equip the PAD to defraud Aetna into paying for excessive dosages of off-label Subsys prescriptions.⁸

Plaintiffs assert the following claims against all Defendants: insurance fraud in violation of 18 Pa. C.S.A § 4117(a)(2) (Count I); aiding, abetting, soliciting, and conspiring to commit insurance fraud in violation of 18 PA. C.S.A. § 4117(a)(3) (Count II); civil conspiracy (Count III); common law fraud (Count IV); unjust enrichment (Count V); negligent misrepresentation (Count VI); and negligence (Count VII).

II. LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(2)

Pursuant to Federal Rule of Civil Procedure 12(b)(2), a court must grant a defendant's motion to dismiss if the court lacks personal jurisdiction over the defendant. When a defendant files a motion to dismiss for lack of personal jurisdiction, the plaintiff bears the burden of establishing that personal jurisdiction exists.⁹ Once a jurisdictional defense has been raised, "the plaintiff must sustain its burden of proof in establishing jurisdictional facts through sworn affidavits or other competent evidence" of sufficient contacts with the forum state.¹⁰ Such contacts must be established with "reasonable particularity," but need only amount to a prima facie case in favor of personal jurisdiction.¹¹ If the plaintiff meets this burden, the defendant

⁷ *Id.* at ¶ 199, 201.

⁸ *Id.* at ¶ 206.

⁹ *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316 (3d Cir. 2007) (citing *Gen. Elec. Co. v. Deutz AG*, 270 F.3d 144, 150 (3d Cir. 2001)).

¹⁰ *Time Share Vacation Club v. Atlantic Resorts, Ltd.*, 735 F.2d 61, 67 n. 9 (3d Cir. 1984); *United Healthcare Servs., Inc. v. Cephalon, Inc.*, No. 17-555, 2018 WL 878766, at *1 (E.D. Pa. Feb. 13, 2018).

¹¹ *Mellon Bank (East) PSFS, Nat'l Ass'n v. Farino*, 960 F.2d 1217, 1223 (3d Cir. 1992); *United Healthcare Servs., Inc.*, 2018 WL 878766, at *1.

must then establish the presence of other considerations that would render jurisdiction unreasonable.¹²

A district court typically exercises personal jurisdiction according to the law of the state where it sits.¹³ Under Pennsylvania’s long arm statute, jurisdiction “may be based on the most minimum contact with th[e] Commonwealth allowed under the Constitution of the United States.”¹⁴ As such, “a court may exercise personal jurisdiction over a nonresident defendant if the defendant has ‘certain minimum contacts with [Pennsylvania] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.’”¹⁵ “Minimum contacts must have a basis in ‘some act by which the defendant purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws.’”¹⁶

Jurisdiction may be general or specific in nature.¹⁷ Here, Aetna relies on specific jurisdiction over Defendants Rowan, Lee, and Fanto. To support a finding of specific jurisdiction, due process requires the plaintiff show: (1) the defendant “purposefully directed its activities at the forum,” (2) the litigation arises out of or relates to at least one of those activities, and (3) the exercise of jurisdiction “otherwise comports with fair play and substantial justice.”¹⁸

¹² *De Lage Landen Fin. Servs.*, 2008 WL 4822033, at *3 (citing *Carteret Sav. Bank v. Shushan*, 954 F.2d 141, 150 (3d Cir. 1992)).

¹³ *O'Connor*, 496 F.3d at 316 (citing Fed. R. Civ. P. 4(k)(1)(A)).

¹⁴ *Id.* (alteration in original) (citing 42 Pa. Cons. Stat. § 5322(b)).

¹⁵ *AAMCO Transmissions, Inc. v. Romano*, 42 F. Supp. 3d 700, 706 (E.D. Pa. 2014) (alteration in original) (quoting *O'Connor*, 496 F.3d at 316).

¹⁶ *Remick v. Manfredy*, 238 F.3d 248, 255 (3d Cir. 2001) (quoting *Asahi Metal Indus. Co., Ltd. v. Superior Court of California*, 480 U.S. 102, 109 (1987)).

¹⁷ *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011).

¹⁸ *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 317 (3d Cir. 2007) (alterations, internal quotation marks, and citations omitted).

B. Federal Rule of Civil Procedure 12(b)(6)

Pursuant to Federal Rule of Civil Procedure 12(b)(6), dismissal of a complaint for failure to state a claim upon which relief can be granted is appropriate where a plaintiff's "plain statement" lacks enough substance to show that he is entitled to relief.¹⁹ In determining whether a motion to dismiss should be granted, the court must consider only those facts alleged in the complaint, accepting the allegations as true and drawing all logical inferences in favor of the non-moving party.²⁰ Courts are not, however, bound to accept as true legal conclusions couched as factual allegations.²¹ Something more than a mere *possibility* of a claim must be alleged; the plaintiff must allege "enough facts to state a claim to relief that is plausible on its face."²² The complaint must set forth "direct or inferential allegations respecting all the material elements necessary to sustain recovery under *some* viable legal theory."²³ In deciding a motion to dismiss, courts may consider "only allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim."²⁴

III. DISCUSSION

A. Personal Jurisdiction

1. Fanto's Motion

Fanto moves to dismiss all claims against him for lack of personal jurisdiction, asserting that he has never practiced medicine in Pennsylvania, has not visited Pennsylvania in over 20

¹⁹ *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007).

²⁰ *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994); *Fay v. Muhlenberg Coll.*, No. 07-4516, 2008 WL 205227, at *2 (E.D. Pa. Jan. 24, 2008).

²¹ *Twombly*, 550 U.S. at 555, 564.

²² *Id.* at 570.

²³ *Id.* at 562 (internal quotation marks and citation omitted) (emphasis in original).

²⁴ *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993); *Brown v. Daniels*, 128 F. App'x. 910, 913 (3d Cir. 2005) (quoting *Lum v. Bank of America*, 361 F.3d 217, 222 n. 3 (3d Cir. 2004)).

years, has never directed marketing efforts towards Pennsylvania, did not have an in-network provider contract with Aetna, and did not submit out-of-network claims to Aetna at any Pennsylvania address.²⁵ In response, Plaintiffs do not assert that Fanto himself purposefully directed activities into Pennsylvania, but contend that personal jurisdiction is proper based on the activities of Fanto's alleged co-conspirators, including Insys and its employees.

Co-conspirator jurisdiction is not a separate basis of jurisdiction apart from general or specific jurisdiction.²⁶ The doctrine merely allows courts to look at the forum-related contacts of a non-resident defendant's co-conspirators to determine if sufficient contacts exist.²⁷ To impute the contacts of a co-conspirator to a defendant, Plaintiffs must plead with particularity that 1) the defendant was a participant in an actionable conspiracy, 2) substantial acts in furtherance of the conspiracy occurred in Pennsylvania, and 3) the non-forum co-conspirator was aware or should have been aware of those acts.²⁸

Here, Plaintiffs have alleged that Fanto conspired with Insys and others to defraud Aetna into paying for off-label prescriptions of Subsys. In support of co-conspirator jurisdiction, Plaintiffs rely on the following overt acts allegedly undertaken by Insys and others in Pennsylvania: 1) "paying kickbacks" to physicians, 2) holding "sham 'speaking events'", 3) prescribing Subsys off-label, and 4) "sending patient medical information to and from Insys' PAD."²⁹ These allegations do not provide a basis for asserting jurisdiction over Fanto. The Complaint does not allege that Insys paid kickbacks to Fanto or held events at which Fanto spoke

²⁵ Fanto Decl. at ¶¶ 3-8, 20-26.

²⁶ *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass'n*, 846 F. Supp. 374, 379 (E.D. Pa. 1994), *aff'd*, 107 F.3d 1026, 1042 (3d Cir. 1997); *United States v. Arrow Med. Equip. Co.*, No. 90-5701, 1990 WL 210601, at *8 (E.D. Pa. Dec. 18, 1990).

²⁷ *Mass. Sch. of Law at Andover, Inc.*, 846 F. Supp. at 379.

²⁸ *Id.* at 379-80; *Arrow Med. Equip. Co.*, 1990 WL 210601, at *8.

²⁹ Pl.'s Br. in Opposition to Fanto and Rowan's Mot. to Dismiss at 14 (citing Compl. ¶¶ 219-23).

in Pennsylvania, and there are no facts in the Complaint suggesting that Fanto knew or should have known of kickbacks or speaker events involving other physicians that took place in Pennsylvania. Similarly, the Complaint does not allege any facts suggesting that Fanto conspired with or was otherwise was aware of health care providers located in Pennsylvania who prescribed Subsys off-label and sent patient medical information to Insys's PAD. Finally, Insys's PAD facilities were located in Arizona, and there are no alleged facts that suggest Fanto should have known that any medical information was being sent from the PAD to Pennsylvania, especially since Aetna has not alleged that any of its facilities or employees that handled claims or authorization requests were located in Pennsylvania. Thus, none of the overt acts alleged to have occurred in Pennsylvania are attributable to Fanto for jurisdictional purposes.

For these reasons, Dr. Fanto's motion is granted, and all claims against him are dismissed for lack of personal jurisdiction.³⁰

2. Rowan and Lee's Motions

Defendants Rowan and Lee also move to dismiss for lack of personal jurisdiction. In asserting jurisdiction, Plaintiffs rely both on the effect of Rowan and Lee's own alleged activities in Pennsylvania and on the co-conspirator theory of jurisdiction.

Courts apply the "effects test" from *Calder v. Jones*,³¹ in analyzing jurisdiction over a non-resident who commits a tort outside of the forum state. The Third Circuit adopted this test in *IMO Industries, Inc. v. Kiekert AG*,³² and stated that to establish jurisdiction, the plaintiff must

³⁰ Personal jurisdiction is assessed on a claim specific basis, see *Remick v. Manfredy*, 238 F.3d 248, 255 (3d Cir. 2001). As mentioned, Plaintiffs have asserted no basis finding purposeful availment based on Fanto's own contacts in connection with any of the asserted counts, and Plaintiffs have provided no authority under which co-conspirator jurisdiction, even if sufficiently pled, would extend to any of the substantive non-conspiracy counts asserted against Fanto.

³¹ 465 U.S. 783 (1984).

³² 155 F.3d 254 (3d Cir. 1998).

show: (1) the defendant committed an intentional tort; (2) the plaintiff felt the brunt of the harm in the forum such that the forum can be said to be the focal point of the harm suffered by the plaintiff as a result of that tort; (3) the defendant expressly aimed his tortious conduct at the forum such that the forum can be said to be the focal point of the tortious activity.³³ To establish that the defendant expressly aimed tortious conduct at the forum state, the plaintiff must identify specific activity indicating such express aim and demonstrate the defendant's knowledge that the plaintiff would suffer the brunt of the harm in the forum.³⁴

In asserting that Rowan and Lee purposefully directed activities toward Pennsylvania, Aetna relies on its allegations that Rowan was the "Director of Sales for the East Region" and Lee was the "Regional Sales Manager for the Mid-Atlantic Region."³⁵ Plaintiffs assert that these management titles create the reasonable inference that Rowan and Lee were responsible for recruiting sham speakers in Pennsylvania. As further support, Plaintiffs point to the single Pennsylvania-based prescriber specifically identified in the complaint, "Prescriber 2," who allegedly spoke at Insys events in this judicial district, and prescribed Subsys to a patient located in Pennsylvania ("Patient C"), whom the PAD fraudulently represented to Aetna had cancer.³⁶

These connections between Defendants and Pennsylvania are too attenuated to establish purposeful availment under *Calder*. First, Plaintiffs have not alleged facts to establish that they suffered the brunt of the harm from Defendants' conduct in Pennsylvania. While Plaintiffs assert that they paid reimbursements for patients located in Pennsylvania, the Complaint does not allege that this is the location where Plaintiffs relied on Defendant's misrepresentation or the

³³ *Id.* at 256.

³⁴ *Id.* at 265-66.

³⁵ Pl.'s Br. in Opp. to Rowan and Fanto's Motion at 13 (citing Compl. ¶¶ 20, 92), Pl.'s Opp. to Lee's Motion at 7 (citing Compl. ¶¶ 19, 22).

³⁶ Compl. ¶¶ 219-23.

location where Plaintiffs suffered economic loss.³⁷ Second, Plaintiffs have not alleged sufficient facts to show that Rowan or Lee directed tortious conduct toward Pennsylvania. While Plaintiffs assert that “[t]he entire purpose” of Defendants’ recruitment of physicians for speaker program “was to [encourage them to] overprescribe Subsys to patients in Pennsylvania so that Aetna would pay for those prescriptions under fraudulent pretenses in Pennsylvania,”³⁸ there are no allegations in the Complaint or other evidence to show that Rowan or Lee specifically directed their promotional efforts at Pennsylvania physicians. Moreover, to the extent Aetna Inc. asserts that it was targeted by the Defendants as a Pennsylvania corporation, Plaintiffs have not alleged that Rowan or Lee directed their recruiting efforts to physicians who provided care to Aetna members.

Moreover, Plaintiffs cannot assert conspiracy jurisdiction over Rowan or Lee because the Complaint does not sufficiently allege facts to support that either Defendant entered into an actionable conspiracy.³⁹ Under Pennsylvania law, a cause of action for civil conspiracy requires 1) a combination of at least two individuals acting with a common purpose of committing a criminal act or intentional tort, 2) an overt act in furtherance of this agreement, and 3) actual legal damage to the plaintiff.⁴⁰ The plaintiff must also allege that the conspirators acted with

³⁷ Neither Plaintiff alleges that it is headquartered in Pennsylvania, conducted review of authorization requests in Pennsylvania, or received or paid claims through a location in Pennsylvania.

³⁸ Pl.’s Br. in Opp. to Rowan and Fanto’s Motion at 13; Pl.’s Br. in Opposition to Lee’s Motion at 7.

³⁹ *Arrow Med. Equip. Co.*, 1990 WL 210601, at *8 (“To satisfy the conspiracy theory of personal jurisdiction, Plaintiff must allege that defendants entered into an actionable conspiracy . . .”). *See also Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 102 n. 8 (3d Cir. 2004) (rejecting the plaintiff’s conspiracy theory of jurisdiction on the grounds that the plaintiff failed to allege an actionable conspiracy). As noted with respect to Fanto, *supra* n. 30, any co-conspirator jurisdiction over Lee and Rowan, even if sufficiently pled, would appear to be limited to the civil conspiracy claim against them.

⁴⁰ *Kline v. Sec. Guards, Inc.*, 386 F.3d 246, 262 (3d Cir. 2004); *Com. ex rel. Pappert v. TAP Pharm. Prods., Inc.*, 885 A.2d 1127, 1140 (Pa. Commw. Ct. 2005) (citation omitted); *Lilly v. Boots & Saddle Riding Club*, No. 57 C.D. 2009, 2009 WL 9101459, at *5 (Pa. Commw. Ct. July 17, 2009).

malice, *i.e.*, that they “took unlawful actions with the specific intent to injure the plaintiff.”⁴¹

Here, the Complaint does not allege that either Rowan or Lee intentionally directed any actions against Aetna. The Complaint does not allege facts to show that either Defendant was aware of the PAD’s alleged fraudulent statements made to Aetna or that either Defendant targeted Aetna members or their physicians. The only employees of Insys specifically alleged to have directed tortious activities toward Aetna are staff members of the PAD, and the only specific alleged involvement by either Rowan or Lee with the PAD is in directing PAD staff members to obtain medical records from physician offices. This alone does not support a specific intent to injure Aetna.

Accordingly, Rowan’s and Lee’s Motions to Dismiss for lack of personal jurisdiction will be granted, and the Court need not reach these Defendants’ other asserted grounds for dismissal.

3. Insys’s Motion to Dismiss

1. Preemption

The doctrine of preemption is rooted in the Supremacy Clause of the United States Constitution, which provides that the “Constitution, and the laws of the United States . . . shall be the supreme Law of the Land.”⁴² Insys asserts that Aetna’s common law claims (Counts III-VII) are preempted by the Federal Drug and Cosmetics Act (“FDCA”) because they are attempts to enforce FDA requirements using state law claims.

There are three primary forms of preemption: (1) “express” preemption, when Congress explicitly states its intent to preempt state law; (2) “field” preemption, when Congress’ intent to preempt state law in particular area is inferred from either the comprehensive scheme of federal regulation in that area or the dominant federal interest in that area; and (3) “conflict” or

⁴¹ *Montgomery Cnty., Pa. v. MERSCORP, Inc.*, 904 F. Supp. 2d 436, 453 (E.D. Pa. 2012) (citing *Commonwealth v. TAP Pharm.*, 36 A.3d 1112, 1185 (Pa. Commw. Ct. 2011).

⁴² U.S. Const. art. VI, cl. 2.

“implied” preemption, when “state law is nullified to the extent that it actually conflicts with federal law,” even though Congress has not displaced all state law in that area.⁴³ Insys relies on a theory of implied preemption articulated by the Supreme Court’s in *Buckman Co. v. Plaintiffs’ Legal Committee*.⁴⁴ In *Buckman*, the Supreme Court held that “state-law fraud-on-the-FDA claims,” based solely on allegations of harm resulting from misrepresentations made to the FDA, “conflict with, and therefore are impliedly pre-empted by federal law.”⁴⁵ The Court reasoned that the statutory and regulatory framework by which the FDA regulates the marketing and distribution of medical devices, including the Agency’s responsibility to police fraud, aim to achieve a “delicate balance of statutory objectives,” which can be skewed by attempts to enforce FDA requirements through state common law.⁴⁶ Insys contends that the same rationale extends to Aetna’s common law claims because they “arise solely from Insys’s allegedly improper off-label promotion of Subsys®,” and are thus attempts to enforce FDA restrictions on the promotion of prescription drug.

Under a fair reading of the Complaint, however, Plaintiffs’ common law claims do not “arise solely from” Insys’s alleged off-label promotion of Subsys and are “not based simply on some regulatory duty owed to the FDA, the breach of which caused injury to the Plaintiffs.”⁴⁷

⁴³ *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 566 (E.D. Pa. 2008) (quoting *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 261 (3d Cir. 2008)); *Deweese v. Nat’l R.R. Passenger Corp.*, 590 F.3d 239, 245 (3d Cir. 2009).

⁴⁴ 531 U.S. 341, 348 (2001).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *In re Tylenol (Acetaminophen) Mktg.*, No. 2436, 2015 WL 7076012, at *8–9 (E.D. Pa. Nov. 13, 2015). There is also no binding authority in the Third Circuit holding that claims based solely on off-label promotion of prescription drugs would be preempted under *Buckman*, although courts in other circuits have so held. *See Wright v. Medtronic, Inc.*, 81 F. Supp. 3d 600, 614 (W.D. Mich. 2015) (“Plaintiff’s negligence allegations based solely on illegal off-label promotion are impliedly preempted because any claim that Defendants engaged in illegal off-label marketing of the Infuse device ‘exists solely by virtue’ of federal regulations, and is not rooted in any traditional state tort law.”); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1178 (C.D. Cal. 2013) (“Any negligence claim based solely on illegal off-label promotion is impliedly preempted”); *Markland v. Insys Therapeutics, Inc.*, 270 F. Supp. 3d 1318, 1330 (M.D. Fla. 2017) (“Because the existence of off-label promotion is a critical element in his

Rather, each of Aetna's negligence, fraud, conspiracy, and unjust enrichment claims relies on material misrepresentations *made directly to Aetna* in circumvention of Aetna's own preauthorization requirements. Notwithstanding any overlap between Aetna's preauthorization requirements for Subsys and the FDA's limitations on the promotion and approved use of Subsys, Aetna's claims are based on Insys's state law duties to refrain from misrepresentation, which exist independently of FDA regulations. Moreover, to the extent the Complaint alleges off-label promotion efforts by Insys, these allegations are asserted as overt acts in an alleged conspiracy to defraud Aetna, not as independently actionable bases for Plaintiffs' claims. Thus, Plaintiffs' common law claims are not preempted under *Buckman*.

Insys also moved the Court, in the alternative, to dismiss Plaintiffs' common law claims on the ground that the FDCA creates no private right of action against off-label promotion.⁴⁸ However, because Plaintiffs' common law claims are based on breaches of duties created under state law, the absence of a private right of action under the FDCA has no bearing on these claims.

2. Economic loss doctrine

Insys contends that all of Plaintiffs' common law claims are barred by the economic loss doctrine because they rely solely on economic damages in the absence of physical injury or property damage. Under Pennsylvania law, the doctrine provides that "no cause of action exists

case, [the plaintiff's] claim is preempted.") (original alterations and citations omitted). However, as discussed *infra* n. 48, courts in this Circuit have held that such claims would fail in the absence of other asserted state law duties because of the FDCA does not create a private cause of action for off-label promotion.

⁴⁸ *Zafarana v. Pfizer, Inc.*, 724 F. Supp. 2d 545, 553 (E.D. Pa. 2010) (holding, with respect to state common law claims based on off-label promotion, that "the FDCA does not preempt other causes of action, but simply does not provide a private cause of action."); *see also Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 544 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3d Cir. 2015)) ("Where off-label promotion violates the FDCA, it is subject to federal regulatory action by the FDA, or enforcement actions by the Department of Justice, but violations of the FDCA do not create private rights of action.").

for negligence that results solely in economic damages unaccompanied by physical injury or property damage.”⁴⁹

Pennsylvania courts have generally applied the economic loss doctrine to negligence-based tort claims such as Plaintiffs’ negligent misrepresentation and negligence claims.⁵⁰

Plaintiffs contend that the bar should not apply here because Defendants’ duties do not flow from a contract. However, while some courts have at times formulated the economic loss doctrine as barring plaintiffs from “recover[ing] in tort economic losses to which their entitlement flows only from a contract,”⁵¹ courts in this district and the Pennsylvania Superior Court have repeatedly held that contractual privity is not a prerequisite for the application of the doctrine.⁵²

In asserting that the doctrine is limited to claims arising from contractual duties, Plaintiffs rely primarily on *Bilt-Rite Contractors, Inc. v. The Architectural Studio*,⁵³ in which the Pennsylvania Supreme Court held that the plaintiff’s negligent misrepresentation claim pursuant to § 522 of the Restatement (2d) of Torts (entitled “Information Negligently Supplied for the Guidance of Others”) was not barred by the economic loss doctrine because the defendant, an architectural firm, owed a common law duty of care as a supplier of professional information for use by others.⁵⁴ Here, Aetna’s negligence and negligent misrepresentation claims would not fall under § 522 because the Complaint does not allege any basis for finding that Insys, as a

⁴⁹ *Excavation Techs., Inc. v. Columbia Gas Co. of Pennsylvania*, 604 Pa. 50, 52 n. 3 (2009). The parties agree that Pennsylvania law applies to Plaintiffs’ common law claims.

⁵⁰ *Excavation Technologies, Inc.*, 936 A.2d 114-15 (“[F]or common law negligent misrepresentation claims the economic loss rule still applies.”); *Adams v. Copper Beach Townhome Communities, L.P.*, 816 A.2d 301, 305-06 (Pa. Super. Ct. 2003).

⁵¹ *Debbs v. Chrysler Corp.*, 810 A.2d 137, 164 n. 32 (Pa. Super. 2002); *see also Werwinski v. Ford Motor Co.*, 286 F.3d 661, 671 (3d Cir. 2002).

⁵² *See Am. Stores Properties, Inc. v. Spotts, Stevens & McCoy, Inc.*, 678 F. Supp. 2d 328, 333-34 (E.D. Pa. 2009) (citing cases from the Eastern District of Pennsylvania and the Pennsylvania Superior Court).

⁵³ 581 Pa. 454 (2005).

⁵⁴ *Id.* at 484.

pharmaceutical manufacturer, owed a professional duty to present accurate information concerning the medical records of patients who are prescribed its products. To the contrary, Aetna asserts that Insys's employees and agents in the PAD deliberately impersonated members of medical offices while providing patient information to Aetna.

Plaintiffs urge the Court to interpret *Bilt-Rite* as exempting all tort claims arising independently of contractual duties from the economic loss doctrine.⁵⁵ However, the Third Circuit has rejected this reading of *Bilt-Rite*, holding that *Bilt-Rite* only created a narrow exception to the doctrine for claims arising from the advice of professionals brought under § 522.⁵⁶ The Pennsylvania Superior Court, in an opinion affirmed by the Pennsylvania Supreme Court, articulated a similar interpretation of *Bilt-Rite* in declining to extend the decision's holding to a negligent representation claim alleging losses caused by information provided by a utility company.⁵⁷ In light of this authority, the Court will apply the economic loss doctrine to Plaintiffs' negligent misrepresentation and negligence claims, and Counts VI and VII of the Complaint will be dismissed.

⁵⁵ Plaintiffs misattribute the statement that the doctrine applies "only in cases where the source of the duty plaintiff seeks to enforce arises from a contract and, even then, only instances where the harm suffered is limited to economic loss arising from the interference with contractual expectation" to *Bilt-Rite*. Pl.'s Br. in Opposition to Insys's Motion at 8. The quote comes from a party's interpretation of *Bilt-rite* as quoted in *Longenecker-Wells v. Benecard Servs. Inc.*, 658 F. App'x 659, 661 (3d Cir. 2016).

⁵⁶ See *Longenecker-Wells v. Benecard Servs. Inc.*, 658 F. App'x 659, 662 (3d Cir. 2016) ("we decline to hold that Pennsylvania's economic loss doctrine is inapplicable here simply because Plaintiffs are not in contractual privity with [the defendant] and thus have no contractual remedy"); *Azur v. Chase Bank, USA, Nat. Ass'n*, 601 F.3d 212, 224 (3d Cir. 2010) (holding that the plaintiff's "contention that the *Bilt-Rite* exception encompasses all cases in which the plaintiff has no contractual remedy is without support"); *Sovereign Bank v. BJ's Wholesale Club, Inc.*, 533 F.3d 162, 177 (3d Cir. 2008) ("The Pennsylvania Supreme Court [in *Bilt-rite*] never suggested that it intended to severely weaken or undermine the economic loss doctrine in a case such as this. It simply carved out a narrow exception when losses result from the reliance on the advice of professionals.")

⁵⁷ See *Excavation Technologies, Inc.*, 936 A.2d 116 ("We view the Supreme Court's adoption of Section 552 as drawing a narrow exception to the application of the economic loss rule in the particular set of circumstances that were present in *Bilt-Rite*."), *aff'd*, 604 Pa. 50 (2009).

The parties further disagree as to whether the economic loss doctrine extends beyond negligence-based torts to intentional torts such as Plaintiffs' common law fraud and conspiracy claims.⁵⁸ While there remains ambiguity in the case law concerning the general applicability of the doctrine to intentional torts, courts in this district have generally agreed that the doctrine does not apply to intentional fraud claims where the alleged misrepresentations at issue are "extraneous" to the terms of any contract between the parties.⁵⁹ Here, because Plaintiffs have not alleged a contractual relationship with any of the Defendants or identified any contractual obligations from which their tort claims arise, the economic loss doctrine does not bar Plaintiffs' claim for common law fraud or civil conspiracy as alleged in Counts III and IV.

Additionally, Defendants have provided no authority for applying the economic loss doctrine to unjust enrichment claims under Pennsylvania law, and the Court is aware of none. Thus, the Court will not dismiss Count V on this ground.

3. Civil Conspiracy

Insys contends that Plaintiffs failed to state a civil conspiracy claim because the Complaint does not allege that Insys acted with the requisite malice. In particular, Insys contends that malice exists only when "the *sole* purpose of the conspiracy was to injure the Plaintiffs,"⁶⁰ and any assertion of malice as to Insys is negated by allegations demonstrating that the company was motivated by its business objectives of increasing profit and market share.

⁵⁸ As discussed further below, civil conspiracy is an intentional tort because it requires specific intent to injure the plaintiff.

⁵⁹ *Werwinski v. Ford Motor Co.*, 286 F.3d 661, 671 (3d Cir. 2002).

⁶⁰ *Zafarana*, 724 F. Supp. 2d at 559 (emphasis in original) (quoting *Morilus v. Countrywide Home Loans, Inc.*, 651 F. Supp. 2d 292, 313 (E.D. Pa. 2008)).

The parties, and courts in this District, disagree over whether motivations of personal or professional gain negate malice for purposes of establishing civil conspiracy.⁶¹ In particular, courts have relied on differing interpretations of the following language in *Thompson Coal Co. v. Pike Coal Co.*,⁶² in which the Pennsylvania Supreme Court affirmed the grant of summary judgment on a civil conspiracy claim on the grounds that the plaintiff failed to establish malice:

Proof of malice, *i.e.*, an intent to injure, is essential in proof of a conspiracy. This unlawful intent must be absent justification. The test was stated in *Rosenblum v. Rosenblum*, 181 A. 583, 585 (1935):

Assume that what is done is intentional, and that it is calculated to do harm to others. Then comes the question, Was it done with or without “just cause or excuse”? If it was bona fide done in the use of a man’s own property . . . such legal justification would . . . exist not the less because what was done might seem to others to be selfish or unreasonable. . . . But such legal justification would not exist when the act was merely done with the intention of causing temporal harm, without reference to one’s own lawful gain, or the lawful enjoyment of one’s own rights.

There are no facts of record which indicate that [the defendant] acted solely to injure [the plaintiffs]. To the contrary, there are many facts which indicate that [the defendant] acted solely to advance the legitimate business interests of his client and to advance his own interests.⁶³

While some courts have construed this language as requiring proof that the alleged conspirators acted “solely to injure” the plaintiffs, with no objective of personal gain,⁶⁴ such an interpretation does not comport with the decision’s reasoning.⁶⁵ In *Thompson*, the plaintiffs, who had leased the mining rights in a tract of land, brought a civil conspiracy claim against a competitor who

⁶¹ Compare, *e.g.*, *Zafarana*, 724 F. Supp. 2d at 559 and *Morilus*, 651 F. Supp. 2d at 313, with *PDC Machines Inc. v. Nel Hydrogen A/S*, No. 17-5399, 2018 WL 3008531, at *5 (E.D. Pa. Jun. 15, 2018) (“this Court is persuaded that the fact that a defendant may benefit economically from improper actions undertaken as part of a conspiracy does not necessarily preclude a finding that the defendant acted with malice”) and *Ozburn-Hessey Logistics, LLC v. 721 Logistics, LLC*, 40 F. Supp. 3d 437, 454 n.4 (E.D. Pa. 2014) (noting that the district court decisions requiring a sole purpose of injury, “rely, directly or indirectly, on the Pennsylvania Supreme Court’s decision in *Thompson*—which actually requires a plaintiff to prove an “intent to injure” that lacks “justification.”).

⁶² 412 A.2d 466 (1979).

⁶³ *Id.* at 472 (citations omitted).

⁶⁴ See, *e.g.*, *Zafarana*, 724 F. Supp. 2d at 559; *Morilus*, 651 F. Supp. 2d at 313.

⁶⁵ See *Ozburn-Hessey Logistics*, 40 F. Supp. 3d 437 at 454 n. 4.

purchased those mining rights along with the competitor's attorney and the seller of the rights. In granting summary judgment, the court defines malice as a specific intent to injure without justification. It reasons that a defendant who commits harm is justified if he acted solely to advance legitimate business or personal interests, but not if he acted solely to injure the plaintiff. The court does not hold that a defendant's interest in economic gain would, in itself, justify or negate specific intent to cause injury, particularly if the intended means for achieving such gain were unlawful and illegitimate.⁶⁶

Here, Plaintiffs assert that Insys conspired with physicians to defraud Aetna into authorizing reimbursements for Subsys. At this stage, if the Court accepts as true that Insys employees acted within the scope of their employment and intentionally used false information to induce Aetna to pay claims it otherwise would not have paid, then the Court can reasonably infer that Insys harbored specific intent to injure Aetna that satisfies the malice element of a civil conspiracy claim.⁶⁷ Whether Insys, through its agents, in fact harbored such intent is a factual question to be developed through discovery. But malice would not be negated by an ultimate business objective of increasing business profits if injury to Aetna is the intended means for achieving that end.

For these reasons, Insys's Motion to Dismiss Count III will be denied.

4. Unjust Enrichment

To state a claim for unjust enrichment under Pennsylvania law, a plaintiff must demonstrate that it conferred a benefit on the defendant, that the defendant knew of the benefit

⁶⁶ See *PDC Machines Inc.*, 2018 WL 3008531, at *5 ("Given the *Thompson* court's definition of malice, this Court is persuaded that the fact that a defendant may benefit economically from improper actions undertaken as part of a conspiracy does not necessarily preclude a finding that the defendant acted with malice.").

⁶⁷ See *Giordano v. Claudio*, 714 F. Supp. 2d 508, 534 (E.D. Pa. 2010) (holding, in the context of a defamation claim, that allegations of injurious claims and knowledge of falsity were sufficient to support malice).

and accepted or retained it, and that it would be inequitable to allow the defendant to keep the benefit without paying for it.⁶⁸ Unjust enrichment is not a substitute for failed tort claims in Pennsylvania, but, instead, will generally be used to imply quasi-contract liability.⁶⁹

Insys argues that Aetna has failed to allege that it conferred a benefit on Insys to Aetna's detriment. The Complaint alleges that Aetna paid for prescriptions of Subsys based on misrepresentations made by Insys concerning the indication for which the drug was prescribed and that Insys gained sales revenue and market share as a result of these prescriptions. Courts have found similar facts to satisfy the benefit element of an unjust enrichment claim under Pennsylvania law.⁷⁰ Significantly, Pennsylvania law does not require that the alleged benefit in an unjust enrichment claim be conferred directly by the plaintiff upon the defendant, so long as the benefit is not too attenuated to support equitable relief.⁷¹ While Insys contends that it only received payment for services and products that it provided, and that an equitable remedy is not justified in light of the tort remedies available to Plaintiffs to redress their losses, these are arguments more appropriately addressed on a full factual record. Thus, Insys's Motion to Dismiss as to Count VII will be denied.

5. Punitive Damages

Insys moves to dismiss Plaintiffs' request for punitive damages essentially on the same grounds that it seeks to dismiss Plaintiffs' common law fraud claim. Because the Court will not

⁶⁸ *Mitchell v. Moore*, 729 A.2d 1200, 1203 (Pa. Super. Ct. 1999).

⁶⁹ *Zafarana*, 724 F. Supp. 2d at 560-61 (citing *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 937 (3d Cir.1999); *TAP Pharm. Prods., Inc.* 885 A.2d at 1137).

⁷⁰ *See TAP Pharm. Prod., Inc.*, 885 A.2d at 1137-38 (finding that an increase in the market share of the defendants' prescription drugs resulting from inflated reimbursements issued by the plaintiff as a result of defendants' pricing scheme were sufficient to support an unjust enrichment claim).

⁷¹ *Glob. Ground Support, LLC v. Glazer Enterprises, Inc.*, 581 F. Supp. 2d 669, 676 (E.D. Pa. 2008) (citing *Baker v. Family Credit Counseling Corp.*, 440 F.Supp.2d 392, 420 (E.D. Pa. 2006); *TAP Pharm. Products, Inc.*, 885 A.2d at 1137-38; *D.A. Hill Co. v. CleveTrust Realty Investor*. 573 A.2d 1005, 1009 (1990).

dismiss Plaintiffs' common law fraud claim at this stage of the case, Plaintiffs' request for punitive damages may also proceed.

4. Insys's Motion to Strike

Federal Rule of Civil Procedure 12(f) allows a district court, in its discretion, to “strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.”⁷² Although motions to strike may save time and resources by making it unnecessary to litigate claims that will not affect the outcome of the case, motions to strike generally are disfavored.⁷³ To prevail, the moving party must demonstrate that “the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or [that] the allegations confuse the issues.”⁷⁴

Here, Defendants seek to strike the following paragraphs of the Complaint: ¶¶ 42-47 (discussing the national opioid epidemic); ¶ 54 (quoting the FDA commissioner on regarding the impact of off-label promotion of drugs on public health); ¶ 55 (quoting the Inspector General of the U.S. Department of Health and Human Services on his opinion on the impact of off-label promotion on the drug approval process and medical decision-making); ¶¶ 96-99, 101 (discussing Insys's settlements with Oregon, New Hampshire, and Illinois attorneys general and ongoing litigation with the Arizona attorney general regarding off-label promotion of Subsys). While neither the national opioid crisis nor the practice of off-label drug promotion forms the actionable crux of Plaintiffs' claims, the Court is not persuaded that these facts “have no possible relation to the controversy”⁷⁵ or are so scandalous as to be deliberately derogatory or inflammatory against Insys. Rather, these background facts provide context to the alleged events

⁷² Fed. R. Civ. P. 12(f).

⁷³ *DeLa Cruz v. Piccari Press*, 521 F. Supp. 2d 424, 428-29 (E.D. Pa. 2007).

⁷⁴ *Id.*; see also Wright & A. Miller, *Federal Practice and Procedure*, § 1382, at 809-10, 815 (1969)

⁷⁵ *DeLa Cruz*, 521 F. Supp. 2D at 428.

and practices at issue, and may assist a finder of fact in understanding the claims and defenses in this case. At the pleadings stage, it is premature to assess whether these alleged facts would be sufficiently prejudicial or confusing to warrant exclusion at later stages of the case. Thus, Insys's motion to strike will be denied without prejudice, and Defendants may raise the same concerns later, if warranted, in a *motion in limine* or as otherwise appropriate.

IV. CONCLUSION

For the reasons discussed, Defendants Fanto, Rowan, and Lee's Motions to Dismiss for lack of personal jurisdiction will be granted, and Insys' Motion to Dismiss will be granted with respect to Plaintiffs' negligent misrepresentation and negligence claims (Counts VI and VII), and denied in all other respects. Insys's Motion to Strike will be denied.

An order follows.